



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1600]

Enforcement Policy for Certain (Provisional) Tobacco Products that the Food and Drug Administration Finds Not Substantially Equivalent; Guidance for Industry and Tobacco Retailers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent." This guidance provides information to tobacco retailers on FDA's enforcement policy regarding certain so-called provisional tobacco products that become subject to not substantially equivalent (NSE) orders issued under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, rm. G335, Silver Spring, MD 20993-2000. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which

the guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, rm. G335, Silver Spring, MD 20993-2000, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent." This guidance provides information to tobacco retailers on FDA's enforcement policy regarding certain so-called provisional tobacco products that become subject to NSE orders issued under the FD&C Act. We received several comments to the draft guidance (79 FR 10534, February 25, 2014), and those comments were considered as the guidance was finalized.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent." It does not establish any rights for any person and is not binding on FDA or the public. You can

use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Comments

A. General Information About Submitting Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

B. Public Availability of Comments

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>. As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on <http://www.regulations.gov>. This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category "Individual Consumer" under the field titled "Category (Required)," on the "Your Information" page on www.regulations.gov. For this docket, however, FDA will not be following this general practice. Instead, FDA will post on <http://www.regulations.gov> comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on <http://www.regulations.gov> if you include that information in the body of your

comments. For electronic comments submitted to <http://www.regulations.gov>, FDA will post the body of your comment on <http://www.regulations.gov> along with your State/province and country (if provided), the name of your representative (if any), and the category identifying you (e.g., individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on <http://www.regulations.gov>, but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: September 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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